

510(k) SUMMARY

Light BioSciences, LLC's

GentleWaves Consumer LED Photomodulation Device (K062991)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Light BioScience, LLC
933 First Colonial Road, Suite 204
Virginia Beach, Virginia 23454

Phone: (757) 425-6900
Facsimile: (757) 425-3127

FEB 15 2007

Contact Person: Richard Krupnick

Date Prepared: September 29, 2006

Name of Device and Name/Address of Sponsor

GentleWaves Consumer LED Photomodulation Device

Light BioScience, LLC
933 First Colonial Road, Suite 204
Virginia Beach, Virginia 23454

Common or Usual Name

Lamp, nonheating

Classification Name

Surgical powered laser instrument

Predicate Devices

Light BioScience, LLC's GentleWaves LED Photomodulation System
(K031425)

Intended Use / Indications for Use

The GentleWaves Consumer LED Photomodulation Device is intended/indicated for over-the-counter use in the treatment of periorbital wrinkles and rhytides.

Technological Characteristics

The GentleWaves Consumer is a hand-held device consisting of a low intensity light emitting diode (LED) lamp placed in contact with the skin at a fixed distance determined by its lens cover. The device components include an LED array, a lens, a handpiece, three circuit boards, a power supply enclosure and power supply.

Performance Data

Performance testing of the GentleWaves Consumer demonstrates no significant difference in spectral content as compared to the cleared GentleWaves device (K031425). Thus, performance and safety testing obtained for the cleared GentleWaves is fully applicable to the GentleWaves Consumer. In addition, a user study was performed to confirm that lay users were able to use the GentleWaves Consumer in accordance with its instructions for use.

Substantial Equivalence

The GentleWaves Consumer is as safe and effective as the GentleWaves LED Photomodulation System. The GentleWaves Consumer has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the GentleWaves Consumer and its predicate device raise no new issues of safety or effectiveness. In addition, the difference in indication as an OTC device does not affect the device's therapeutic effect. Thus, the GentleWave Consumer is substantially equivalent.



AUG 18 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Light Bioscience, L.L.C.
% Hogan & Hartson, L.L.P.
Mr. Jonathan S. Kahan
555 Thirteenth Street Northwest
Washington, District of Columbia 20004

Re: K062991

Trade/Device Name: Gentlewaves™ Consumer LED Photomodulation Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHS
Dated: February 15, 2008
Received: February 15, 2008

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of June 26, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized, flowing script.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K062991

Device Name: GentleWaves Consumer LED Photomodulation Device

Indications for Use:

The GentleWaves Consumer LED Photomodulation Device is intended/indicated for over-the-counter use in the treatment of periorbital wrinkles and rhytides.

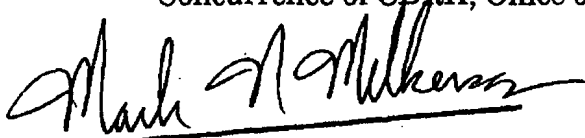
Prescription Use _____
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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